# Agreement Between The United States Environmental Protection Agency and The Hartz Mountain Corporation EPA Registration Nos. 2596-148; 2596-151 (for cats) ("Products")

This Agreement, between the United States Environmental Protection Agency ("EPA" or "Agency") and The Hartz Mountain Corporation ("HM"), is effective the date that the last party signs this Agreement.

- 1. Risk Mitigation Labeling: The parties acknowledge and agree that upon the date this Agreement is signed by both parties, EPA Registration Division (RD) will approve HM's April 19, 2005, application to amend the labels of EPA Registration Nos. 2596-148 and 2596-151 to incorporate agreed-upon risk mitigation labeling including restriction against use on cats 6 pounds or less. No later than June 27, 2005, all Products released for shipment by HM from its own facilities will bear the new label. After August 1, 2005, HM will not sell or distribute from HM facilities Products bearing old labels.
- 2. <u>Submission of Applications for Registration of Replacement Products</u>: HM intends to submit to RD complete applications to register replacement topical Products for cats. If such applications are submitted, RD will use its best efforts to issue a determination on the applications no later than 45 days from receipt of a complete application after HM submits a complete application. EPA will determine completeness of HM application. To assist in expediting the decision-making of state registrations, RD will facilitate concurrent reviews for state registrations.
- 3. <u>Voluntary Cancellation and Amendment</u>: Attachment I to this Agreement is HM's signed irrevocable request for voluntary cancellation of EPA Registration No. 2596-148 and HM's signed amendment of EPA Registration No. 2596-151 to delete the product's uses on cats. Attachment I is effective only upon EPA signing this Agreement.
- 4. <u>Production</u>: HM will cease production of EPA Registration No. 2596-148 Product no later than September 30, 2005. HM will cease production of EPA Registration No. 2596-151 Product with labels containing directions for use on cats no later than September 30, 2005.
- 5. Release for Shipment: After October 31, 2005, HM will not release for shipment from its facilities EPA Registration No. 2596-148. After October 31, 2005, HM will not release for shipment from its facilities EPA Registration No. 2596-151 products that are labeled for use on cats.
- 6. <u>HM Letter to Customers</u>: No later than June 17, 2005, HM will send to each customer (distributors and retailers of Products) Attachment II to this Agreement.
- 7. Existing Stocks: EPA intends to issue a cancellation order in response to HM's voluntary request to cancel EPA Registration No. 2596-148 and amendment of Registration No. 2596-151, as set forth in Attachment I. In any cancellation order or amended registration issued, the order

1

or registration can not have a prohibition date for the use of existing stocks earlier than March 31, 2006. After the existing stocks date, Products may not be distributed unless for the purpose of proper disposal or export. Any Products released for shipment by HM as of October 31, 2005 may not be sold or distributed by HM after December 31, 2005. Commencing April 1, 2006, for a period of six months, HM will provide RD with monthly reports on the status of existing stocks of Products of customers of HM.

- 8. <u>Amendment of Registrations to Incorporate Agreement</u>: The parties acknowledge and agree that this Agreement shall constitute HM's request to amend EPA Registrations 2596-148 and 2596-151 to incorporate this Agreement.
- 9. <u>Amendments</u>: This Agreement may not be amended except solely in a writing signed by both parties hereto.
- 10. <u>Legal Notices</u>: Notices under this Agreement shall be sent by any means but shall not be effective until actually received by the addressee as follows: if to EPA: Michele Knorr, 2333A, USEPA Headquarters, Ariel Rios Building, 1200 Pennsylvania Avenue, Washington, DC 20460, 202-564-5631, <u>knort michele depa.gov</u> and if to HM: Max C. Marx, Esq., Corporate General Counsel & Regulatory Affairs, The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, New Jersey 07094, <u>maxmarx@hartz.com</u>. The parties agree, however, that all registration documents from HM shall be sent to RD.

IN WITNESS WHEREOF, the parties have entered into this Agreement effective the date that the last party signs this Agreement.

For the United States Environmental Protection	For The Hartz Mountain Corporation:
Agency: Lois a. Rossi	Max C. Marx
	Corporate General Counsel & Regulatory Affairs
Date: June 3, 2005	Date: June 3, 2005

### Attachment I

To

## Agreement between EPA And the Hartz Mountain Corporation

On

EPA Registration Nos. 2596-148; 2596-151 (for cats)

Ms. Ann Sibold
PM Team 10
Registration Division
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 226A, Crystal Mall 2
Arlington, VA 22202-4501

#### Re: EPA Registrations EPA Registration Nos. 2596-148; 2596-151 (for cats)

Dear Ms. Sibold:

In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), as amended, The Hartz Mountain Corporation ("Hartz" or "Registrant") submits this voluntary request that EPA, effective no earlier than October 31, 2005: 1) cancel EPA Registration 2596-148 and 2) amend Registration No. 2596-151 by deleting its use on cats (collectively referred to as "Products"). Registrant requests EPA to waive the 180-day Federal Register comment period pursuant to FIFRA § 6(f)(1).

Hartz' request is subject to the following terms and conditions:

- 1. Effective date of cancellation and amendment: The final Agency cancellation order (for EPA Registration No. 2596-148) and the final Agency approval of amendment (of EPA Registration 2596-151) shall provide that the cancellation of EPA Registration No. 2596-148 and the final approval of amendment of EPA Registration No. 2596-151 will not become effective before October 31, 2005.
- 2. Existing Stocks: The final cancellation order (for EPA Registration No. 2596-148) and the final Agency approval of amendment (of EPA Registration 2596-151) shall provide that Products in the United States which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation and amendment may be sold or distributed by Hartz from its facilities until December 31, 2005 and may be sold or distributed by persons other than Registrant until March 31, 2006.

Should you have any questions or comments concerning this matter, please do not hesitate to contact me at 201-271-4800 ext. 7577.

Sincerely,

Douglas A. Rupp Sr. Director Regulatory Affairs

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#### Attachment II

To

## Agreement between EPA And the Hartz Mountain Corporation

On

EPA Registration Nos. 2596-148; 2596-151 (for cats)

Letter to Hartz customers re: flea and tick drops for cats

RE: Changes to Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats (3270098195, 3270098428) and Advanced Care® Flea & Tick Drops 3 in 1 For Cats (3270098451, 3270098429)

#### Dear Customer:

I am writing to inform you that later this year The Hartz Mountain Corporation is planning to discontinue our Advanced Care® Flea & Tick Drops for Cats. Both the Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats are involved in this change. It is our intention to launch a patented replacement cat product for the 2006 season.

Our Advanced Care 3 in 1 and 4 in 1 dog products will remain unchanged, and we will continue to market the leading OTC topical flea and tick treatment for dogs.

These changes are being undertaken following a number of discussions with the Environmental Protection Agency ("EPA") which regulates topical insecticides. Hartz will voluntarily cancel registrations for Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats with an effective date of October 31<sup>st</sup>, 2005.

EPA intends to allow the continued sale of Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats through March 31<sup>st</sup>, 2006.

To allow for an orderly transition to the new replacement cat product, the following are the critical dates that you need to be aware of:

- October 31<sup>st</sup>, 2005: Hartz will not accept orders after this date for the Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats. Given that we intend to have a new replacement cat product for the 2006 season, we recommend that you only order your product needs through December 31<sup>st</sup>, 2005.
- March 31<sup>st</sup>, 2006: It is our understanding that the EPA will allow Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats to continue to be sold until this date. In order to have all of this product removed from warehouses and retail shelves by March 31<sup>st</sup>, 2006, as required by the EPA, Hartz

will be working with you. This will allow an orderly transition to the new replacement cat product.

Additionally, Hartz is making three enhancements to the existing label language for the Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats. These label changes will provide more specific directions to pet owners on appropriate use of the product. Those enhancements are as follows:

Current label:

Do not use on aged cats

Revised Label:

Do not use on cats older than 13 years of age

Current label:

Do not use on kitten less than 12 weeks old

Revised Label:

Do not use on cats or kittens less than 5 months of age (20 weeks)

Current label:

No weight restriction

Revised Label:

Do not use on cats or kittens 6 pounds or less

All Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats shipped starting June 27<sup>th</sup>, 2005 will have the new labels.

In summary, Hartz will be requesting that the current and revised Advanced Care® Flea & Tick Drops Plus 4 in 1 for Cats and Advanced Care® Flea & Tick Drops 3 in 1 for Cats products be canceled conditioned upon the EPA authorizing continued sale through March 31<sup>st</sup>, 2006. Final orders for these products must be placed by October 31<sup>st</sup>, 2005. Hartz will be working with you to ensure all products are removed from distribution by March 31<sup>st</sup>, 2006. This will allow an orderly transition to our new replacement product.

Your Hartz sales representative will be contacting you to discuss the details of the transition.

We continue to appreciate your support of Hartz products.

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